Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the efficacy of Atorvastatin in the management of critically ill COVID-19 patients: A Randomized-controlled clinical trial

Protocol summary

Study aim

1. Determining and comparison of the number of patients with clinical improvement and treatment failure at the end of the fifth, tenth, and fourteenth days of intervention, between study groups (the experimental and control groups) 2. Determining and Comparison of the mean CRP and IL-6 at the end of the fifth, tenth, and fourteenth days of intervention, between study groups (the experimental and control groups) 3. Determining and comparison of the number of intubated patients between study groups (the experimental and control groups) at the end of the study

Design

Two arms parallel-group randomized trial with control group design of 60 patients, phase 3. Block randomization was carried out by computer.

Settings and conduct

This study will be a randomized -controlled clinical trial to evaluate the effectiveness of atorvastatin in the treatment of Covid patients admitted to the intensive care unit of eligible hospitals for hospitalized Covid-19 patients affiliated to Isfahan University of Medical Sciences.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18 years or older Diagnosis of COVID-19 Hospitalization in the intensive care unit Full consent and acceptance of the patient or their legal guardian to recruit in the study Possibility to follow the patient for at least seven days Exclusion criteria: Contraindications of atorvastatin administration Malignancy or immune deficiency Patients under mechanical ventilation

Intervention groups

Intervention group: In addition to the essential treatment for COVID-19, one tablet of atorvastatin 20 mg daily will be administered for 14 days. Control group: Standard and essential treatment for COVID-19

Main outcome variables

Clinical improvement

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150221021159N7**
Registration date: **2021-11-10, 1400/08/19**
Registration timing: **registered_while_recruiting**

Last update: **2021-11-10, 1400/08/19**
Update count: **0**

Registration date

2021-11-10, 1400/08/19

Registrant information

Name
Shadi Farsaei

Name of organization / entity
Isfahan University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 31 3792 2618

Email address
farsaei@pharm.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-23, 1400/08/01

Expected recruitment end date

2022-04-21, 1401/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluation of the efficacy of Atorvastatin in the management of critically ill COVID-19 patients: A Randomized-controlled clinical trial

Public title
Effect of Atorvastatin in the management of COVID-19
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age 18 years or older Diagnosis of COVID-19 by RT PCR test and CT scan of the lung and the opinion of the specialist physician Hospitalization in the intensive care unit Full consent and acceptance of the patient or their legal guardian to recruit in the study Possibility to follow the patient for at least 7 days
Exclusion criteria:
Contraindications to the use of atorvastatin include allergic reactions to the drug, active liver disease or persistent and unexplained increase in liver enzymes, pregnancy and lactation, severe hepatic or renal insufficiency (clcr <30 ml / min) Malignancy or underlying immunodeficiency or concomitant use of immunosuppressive drugs Intubated patient under care with mechanical ventilation
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization with the permuted block method was used to create the random sequence in each group. At first, the specific internet software (https://www.sealedenvelope.com/simple-randomiser/v1/lists) was used to create the random series in blocks of 2, 4, and 6. Each block has an equal number of melatonin and control groups. After that, created codes were written on the cards and placed respectively for hiding in locked opaque packets. A packet was selected for each patient according to the study recruitment, which determines the related study group.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
Street address
Department of clinical pharmacy and pharmacy practice, faculty of pharmacy, Isfahan University of Medical Sciences, Hezar Jarib Ave. Isfahan University of Medical Sciences.
City
Isfahan
Province
Isfehan
Postal code
۷۳۴۶۱-۸۱۷۴۶
Approval date
2021-09-19, 1400/06/28
Ethics committee reference number
IR.MUI.MED.REC.1400.492

Health conditions studied

1

Description of health condition studied
COVID-19
ICD-10 code
B34.2
ICD-10 code description
Coronavirus infection, unspecified

Primary outcomes

1

Description
Clinical improvement of COVID-19
Timepoint
Day: 1, 3, 7 and 14
Method of measurement
APACHE score, evaluation of vital signs، relevant laboratory and arterial blood gas analysis.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In addition to the essential and standard treatment for COVID-19, one tablet of atorvastatin 20 mg (Abidi pharmaceutical company), once daily will be administered for 14 days.
Category
Treatment - Drugs

2

Description
Control group: Standard and essential treatment for COVID-19
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-Zahra Hospital
Full name of responsible person
Shadi Farsaei
Street address
Sofeh Boulevard - Al-Zahra Educational and Medical Center
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farsaei@pharm.mui.ac.ir
Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Shaghayegh Haghjou Javanmard
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Hezar Jerib St., Isfahan University of Medical Sciences and Health Services, Central Headquarters
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research@mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Shadi Farsaei
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Not applicable